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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,147	12/07/2001	Frank Blecha	23625-DIV1	7389

7590 09/15/2005

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,147	BLECHA ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 4-8* is/are allowed.

6)☒ Claim(s) *2 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 6/28/05, claims 2 and 12 have been amended. Claims 1, 2, 4-8, 12-17 remain pending. Claim 2 is now rejoined with the elected group. Claims 1, 2, 4-8, 12-17 are examined in this Office action.

Applicants' arguments filed 12/14/04 have been considered and found not persuasive.

✧

The specification is objected to. On page 1 of the application, the continuity status is provided. However, there is no reference to PCT/US96/04674. It is suggested that applicants amend the first paragraph of page 1 (of the specification) to make reference to this document.

✧

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 12 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 recites that the peptide has between 15 and 39 amino acids, and at the same

time, has at least 15 contiguous amino acids of the peptide of SEQ ID NO: 1. However, there does not appear to be descriptive support for this. Applicants are requested to point to the page and line number(s) where support can be found.

In response to the foregoing, applicants have argued that the contents of USP 5830993 have been incorporated by reference, and that at col 2, line 4+, this patent makes reference to a peptide that contains at least 15 amino acids of SEQ ID NO: 1, beginning at the amino terminal thereof. These two points are correct. However, the patent at issue (5,830,993) makes no mention of attracting leukocytes to the location of a wound; instead, the peptides in question are described only as having the property of inhibiting bacterial growth. In the specification as filed, there is no statement that the peptides which are disclosed in USP 5,830,993 can be used to attract leukocytes to the location of a wound. And even if there were such a statement present, the passage in question (col 2, line 4+ of USP '993) requires that the amino terminus of SEQ ID NO: 1 be present in any of the derivative peptides; thus, for example, the following peptide subsequence would have to be present at the N-terminus: RRRPRPP...

Similar to the foregoing, claim 2 recites new matter. This claim contains a typographical error, and it is not clear exactly what applicants intend. At the present time, it is assumed that applicants intend to recite, in essence, a 15-mer subsequence that is present in SEQ ID NO: 1, or any peptide that contains such a subsequence. If this

is the intention, the claim constitutes new matter.

✦

Claims 12-17 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 12 is drawn to a method of attracting a leukocyte to a wound location, or to an area of inflammation. According to what is asserted by the claim, any leukocyte can be attracted to any location, irrespective of the route of administration, or the anatomical site of administration. The phrase "attracting leukocytes to a [specific] location" implies that there will be more leukocytes at the target site than at all other sites. However, it is far from clear how this might be achieved. For example, if the spinal cord is inflamed, would the peptide migrate specifically to the spinal cord merely as a result of intravenous administration of the peptide? Or suppose that there is a fungal infection on a person's foot, resulting in inflamed tissue at that location. Would intracerebral administration of the peptide cause the peptide to migrate specifically to the foot? Or suppose that a person's eye is inflamed. Would intradermal administration of the peptide via a "patch" on the person's back cause the peptide to migrate to the eye?

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400,

Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

There is no evidence that the peptide, once administered, will demonstrate any preference for tissues that are inflamed or wounded. There are no "working examples" which show this, and no evidence from the prior art to support such an assertion.

In response to this, applicants have argued that on page 14, lines 5-12, it is asserted that if a skilled immunologist administers one of the peptides (to which the claims are drawn) to an animal that has been wounded, the peptides somehow induce leukocytes to migrate to the site of the wound, and that the migration thus induced is greater than would have been the case had the peptide not been administered. However, the passage at issue states nothing of the kind. It may be that applicants were able to devise an in vitro assay which demonstrates chemotaxis in a Petri dish. But the intact animal is another matter. There is no indication that the peptides themselves will accumulate at the site of injury, or that if they did, they would succeed in increasing the number of leukocytes migrating thereto.

As a preliminary matter, it is suggested that applicants point to the location where it is shown experimentally that the peptides themselves will migrate to the site of injury.

This will then provide the basis for further discussion. As matters currently stand, however, it remains the case that "undue experimentation" would be required to practice the claimed invention.

✦

Claims 2 and 12 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 2 recites the following: "at least 15 contiguous amino acids how wfrom" Clearly, the phrase "how wfrom" is not intended. Correction of this typographical error is required. At the present time, it is assumed that applicants intend to convey, in essence, a 15-mer subsequence that is present in SEQ ID NO: 1, or any peptide that contains such a subsequence. If this is the case, then claim 2 is not properly subgeneric to claim 1. Claim 1 is drawn to a method of using a peptide. That peptide can be no longer and no shorter than the peptide of SEQ ID NO:l, no longer and no shorter than the peptide of SEQ ID NO:2, no longer and no shorter than the peptide of SEQ ID NO:3, no longer and no shorter than the peptide of SEQ ID NO:5, no longer and no shorter than the peptide of SEQ ID NO:6, and no longer and no shorter than the peptide of SEQ ID NO:7. Claim 2, by contrast, permits many more possibilities than this. This particular ground of rejection can be overcome by casting claim 2 in independent form (the §112, first paragraph rejections, however, will remain).

- Claim 12 is indefinite as to the anatomical site(s) of administration.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800